FEB 1 2 2001

510(k) Summary

1.0 SUBMITTER INFORMATION

1.1 Submitter:

SHIMADZU MEDICAL SYSTEMS

20101 South Vermont Ave. Torrance, CA 90502-1328

PH: 310-217-8855 FX: 310-217-8869

1.2 Contact:

Masaaki Shibata

1.3 Date:

November 10, 2000

2.0 DEVICE NAME

2.1 Proprietary Name:

SDU-2200

2.2 Common Name:

Ultrasound Imaging System

2.3 Classification:

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550, Product Code 90-IYN Ultrasonic Pulsed Echo Imaging System FR # 892.1560, Product Code 90-IYO

Diagnostic Ultrasound Transducer FR # 892.1570, Product Code 90-ITX

2.4 Predicate Device:

GE Logiq 500 (K991611, 6/9/99)

3.0 DEVICE DESCRIPTION

The SDU-2200 is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Color mode, Continuous Doppler mode, or in a combination of modes.

4.0 INTENDED USE

The SDU-2200 is intended for the following applications:

Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

5.0 SAFETY CONSIDERATIONS

SDU-2200 has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment



FEB 1 2 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Masaaki Shibata Ultrasound Project Manager Shimadzu Medical Systems 20101 South Vermont Ave. TORRANCE CA 90502-1328

Re: K003514

SDU-2200 Diagnostic Ultrasound System

Dated: November 10, 2000 Received: November 14, 2000

Regulatory Class: II

21CFR §892.1550/Procode: 90 IYN 21CFR §892.1560/Procode: 90 IYO 21CFR §892.1570/Procode: 90 ITX

Dear Mr. Shibata:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SDU-2200 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

L040-075U 5 – 10 MHz Linear array L040-120U 8 – 15 MHz Linear array L070-075U 5 – 10 MHz Linear array L072-050U 3.5 – 7 MHz Linear array VA13R-035U 2.5 – 5 MHz Convex array, 13 mmR VA13R-050U 3.5 – 6 MHz Convex array, 13 mmR VA20R-035U 2.5-5.5 MHz Convex array, 20 mmR VA40R-035U 2 – 5 MHz Convex array, 40 mmR VA40R-035HU 2 – 5 MHz Convex array, 40 mmR VA57R-0375WU 2 – 5.5 MHz Convex array, 57 mmR VA57R-0375HU 2 – 5.5 MHz Convex array, 57 mmR S017-035U 2-5 MHz Sector array S011-050U 3.5-7 MHz Sector array TV11R-055U 4 - 8 MHz Transvaginal convex array, 11 mmR UB10R-065U 4 - 8 MHz Transrectal biplane convex array,10 mmR

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for

Daniel G. Schultz, M.D.

Said a Symm

Captain, USPHS

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosures

Prescription Use (Pe	er 21 sour	CFR id De	801. evic	109) e Indio	cations	Stateme	nt Page	_1 of .	_16		
510(k) Number (if k Device Name : <u>Dia</u>	nouz	a) ·									
Fill out one											
Indications for use:	Dia	gnost	ic ult	rasoun	d imagi	ng or Dopp	oler analysis o	of the huma	n body as foll	lows:	1+
						e of Operat					
	T**			DWD	CWD	Color	Power	Color	Combined	Tissue	Other
Clinical Application	A	В	М	PWD	CWD	Doppler	(Amplitude) Doppler	Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
Ophthalmic	<u> </u>				ļ		ļ	3.7	 	N	
Fetal		N	N	N	ļ	N	N	N	N	N	
Abdominal		N	N	N	<u> </u>	N	N	N	- N	111	
Intra-operative (Specify)										<u> </u>	
Intra-operative					1		1	Ì	1		
Neurological	<u> </u>	<u> </u>				ļ <u>.</u>	 	NT.	N		
Pediatric	<u> </u>	N	N	N	N	N	N	N_	18	┼┈┈	
Small Organ	1	N	N	N		N	N	N	N		
(Specify) *			 		 -	<u> </u>		 		 	
Neonatal						ļ			-		
Cephalic	ļ	-	ļ	 	 					1	
Adult Cephalic	 	I N	N	N	N	N	$\frac{1}{N}$	N	N	N	
Cardiac	╁—	N	IN	IN IN	13	1	1	 			
Transesophageal	-	N	N	N	-	N	N	N	N		
Transrectal		N	N	N	+	$\frac{1}{N}$	N	N	N		
Transvaginal Transurethral	+	14	11	11	 	 					
Intravascular	 		 	-		 					
Peripheral Vascular		N	N	N	 	N	N	N	N		
Laparoscopic	+	11	1		-						
Musculo-skeletal	+	N	N	N	1-	N	N	N	N		
Conventional			* '								
Musculo-skeletal	1	N	N	N		N	N	N	N		
Superficial										•	
Other (Specify)	<u> </u>										<u> </u>
N= new indication;	P= 1	orevio	ously	cleared	by FD	A; E= adde	ed under App	endix E			
<u> </u>	, 1		-		•						
Other Indications of	or Mo	des:									-
* Thyroid, Testicle	s, Br	east									-
** B/M, B/PWD, 0	CFM((B)/P	WD,	CFM(E	3)/CFM	(M)					-
											-
			107	IDITED DO	LOW TITE	L DIE CONT	INUE ON ANOTH	ER PAGE IE N	FEDED)		-
	PLEA	SE DO	NOT W	Oncurrence	e of CDRI	I, Office of Dev	vice Evaluation (Ol	DE)			-
One carintian	. 91	:0		1							

510(k) Number (if know Device Name: Diagnos Fill out one form Indications for use: Diagnos Clinical Application A Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological	tic Ul	each	ultraso	und sys d imagi Mode	tem or tran	isducer.	f the huma	n hadv as fall		
Indications for use: Dia Clinical Application A Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological	agnos	tic ul	trasoun	d imagi Mode	ng or Dopp		f the huma	n hadv as fall		
Clinical Application A Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological		.	-uah*	Mode		oler analysis o	f the huma	n hady as fall		
Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological	В	М	PWD					ii bouy as ion	ows:	
Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological	В	М	PWD		of Operat			T-11	T	1 04
Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological		T		CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological		L						<u> </u>		
Intra-operative (Specify) Intra-operative Neurological			·							
Intra-operative (Specify) Intra-operative Neurological										
Intra-operative Neurological										
Neurological										
				1						1
Pediatric	1	<u> </u>								
Small Organ	1	1		1.		N	N	N		
(Specify) *	N	N	N		N	N	N	IN		
Neonatal			1				ĺ			
Cephalic	┼─	┼	ļ						 	
Adult Cephalic	-	-	ļ	 	ļ				 	<u> </u>
Cardiac	—	—		ļ					 	
Transesophageal		 	ļ	-					 	
Transrectal		ļ	<u> </u>	ļ					1	<u> </u>
Transvaginal		 	ļ						ļ	
Transurethral				ļ						ļ
Intravascular					<u> </u>				ļ	
Peripheral Vascular	N	N	N		N N	N	N	N	ļ	
Laparoscopic			<u> </u>							<u> </u>
Musculo-skeletal	N	N	. N		N	N	N	N		1
Conventional		<u> </u>			<u> </u>					
Musculo-skeletal	N	N	N		N	N	N	N	1	
Superficial										
Other (Specify)				l					<u> </u>	<u> </u>
N= new indication; P= 1	previo	ously	cleared	by FD	A; E= adde	ed under Appe	endix E			
.,,		•		•						
Other Indications or Mo	odes:									
* Thyroid, Testicles, Br	east									
** B/M, B/PWD, CFM((B)/P	WD,	CFM(E)/CFM	(M)					
	····									
(PLEAS		NOT								
	SE DO	NOLW	RITE BE	LOW THIS	LINE-CONTI	NUE ON ANOTHE	R PAGE IF NE	EDED)		
	SE DO	C	RITE BE	LOW THIS e of CDRH	LINE-CONTI I, Office of Dev	NUE ON ANOTHE rice Evaluation (OD	R PAGE IF NE E)	EEDED)		•

Clinical Application 1 4 R 1 M 1 PWI) Color 1 Ower Color	Clinical Application	Tissue Harmonic	Other (Speci
Clinical Application	Clinical Application A B M PWD CWD Color Doppler (Amplitude) Imaging Doppler Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic	Harmonic	1
Clinical Application A B N Pro Cro Doppler Amplitude Doppler Doppler Amplitude Doppler Doppler Amplitude Doppler Doppler Doppler Amplitude Doppler Doppl	Clinical Application A B M PND CND Doppler (Amplitude) Velocity Imaging Doppler (Amplitude) Pelocity Imaging (Specify)** Velocity Imaging (Specify)** Intra-operative (Specify) Doppler (Amplitude) Doppler (Amplitude) Pelocity Imaging (Specify)** Neurological Doppler (Amplitude) Doppler (Amplitude) Doppler (Amplitude) Pelocity Imaging (Specify)** Neurological Doppler (Amplitude) Doppler (Amplitude) Doppler (Amplitude) Pelocity Imaging (Specify)** Neurological Doppler (Amplitude) Doppler (Amplitude) Doppler (Amplitude) Pelocity Imaging (Specify)** Neurological Doppler (Amplitude) Doppler (Amplitude) Doppler (Amplitude) Pelocity Imaging (Specify)** Neurological Doppler (Amplitude) Doppler (Amp	Harmonic	(Spec
Fetal	Fetal Abdominal Intra-operative (Specify) Intra-operative Intra-operative Neurological Neurological Pediatric Small Organ (Specify) * N N N N N N N N N N N N N N N N N N N		
Fetal	Fetal Abdominal Intra-operative (Specify) Intra-operative Intra-operative Neurological Neurological Pediatric Small Organ (Specify) * N N N N N N N N N N N N N N N N N N N		
Intra-operative	Intra-operative		
(Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Nonatal Cephalic Adult Cephalic Cardiac Transeophageal Transrectal Transvaginal Transverthral Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Specify		
Intra-operative Neurological Pediatric Neurological Pediatric Neurological Neurolo	Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic		+
Neurological	Neurological Pediatric Small Organ N N N N N N N N N N N N N N N N N N N		
Pediatric Small Organ N N N N N N N N N N N N N N N N N N	Pediatric N		
Small Organ	Small Organ N <th< td=""><td></td><td></td></th<>		
Specify * N N N N N N N N N	(Specify) * Neonatal Cephalic Adult Cephalic		
Neonatal Cephalic Adult Cephalic Cardiae Transesophageal Transectal Transvethral Intravascular Peripheral Vascular Musculo-skeletal Musculo-skeletal N N N N N N N N N N N N N N N N N N N	Neonatal Cephalic Adult Cephalic		
Cephalic Adult Cephalic Cardiac Transesophageal Transvectal Transvethral Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Cephalic Adult Cephalic		T
Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Musculo-skeletal Conventional Musculo-skeletal N N N N N N N N N N N N N N N N N N N	Adult Cephalic		
Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N			
Transvaginal Transvaginal Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N			<u> </u>
Transvaginal Transurethral Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Transesophageal		
Transurethral Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N			
Intravascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Transvaginal	ļ	-
Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Transurethral		
Laparoscopic Musculo-skeletal NNNNNNNNNNNNNNNNNNNNNNNNNNNNNNNNNNNN		 	
Musculo-skeletal N N N N N N N N N N N N N N N N N N N	Temperativacuus II II II		
Conventional Musculo-skeletal N N N N N N N N N N N N N N N N N N N		-	
Musculo-skeletal N N N N N N N N N N N N N N N N N N N	Musculo-sketetat		
Superficial Others (Specify) N= new indication; P= previously cleared by FDA; E= added under Appendix E Other Indications or Modes: * Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)			1
Others (Specify) N= new indication; P= previously cleared by FDA; E= added under Appendix E Other Indications or Modes: * Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Museuro-sketetut 11 11		
N= new indication; P= previously cleared by FDA; E= added under Appendix E Other Indications or Modes: * Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)			
* Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)			
* Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Other Indications on Modern		
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)			_
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	, 		_
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	B/N, B/I WD, CIM(B)/I WD, CIM(B)/CIM(M)		-
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)			_
Consumence of CDRH, Office of Device Evaluation (ODE)	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)		_
Concurrence of Colors, Office of Device 2 Manual (C22)			

510(k) Number KCC 35 14

Prescription Use (Per Ultras	21 our	CFR 1d D	801 evi	.109) ce Indi	ication	s Statem	ent Pag	e <u>4</u> of	<u>16</u> .		
510(k) Number (if kr Device Name : <u>Diag</u>	nosi	n) : _ tic U	ltras	ound Sy	ystem S	DU-2200,	<u>L070-075U</u>				pi.
Fill out one	forr	n for	eacl	ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	gnos	tic u	ltrasou	nd imag	ing or Dop	pler analysis	of the hum	an body as fo	llows:	
						le of Opera					
Clinical Application	A	В	М	PWD	CWD	Color	Power	Color	Combined	Tissue	Other
Синси пррисино.						Doppler	(Amplitude) Doppler	Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
0.1.1.1.			-				Боррісі				
Ophthalmic						 -					
Fetal		-	-								
Abdominal					 	 		-			
Intra-operative								1			
(Specify)		-			 		-	<u> </u>			
Intra-operative			٠								
Neurological		-			 		 				
Pediatric		├─-	-		 						
Small Organ		N	N	N		N	N	N	N ·		
(Specify) * Neonatal						l					
1							İ			1	
Cephalic Adult Cephalic		 	 		 						
Cardiac				<u> </u>	 	 		 			
Transesophageal		-	\vdash		-						
Transesopnageat Transrectal		├	 	-		· · · · · · · · · · · · · · · · · · ·					
		┼─	-								
Transvaginal		₩	 								
Transurethral		-	 			 	1	 			
Intravascular		NT	N	N	 	N	N	N	N		"
Peripheral Vascular		N	<u> N</u>	IN	 	1	1	 			
Laparoscopic Musculo-skeletal		N	N	N	┼──	 N	N	$\frac{1}{N}$	N		
Muscuto-sketetat Conventional		IN	14	11		1		1 '`	-		
Musculo-skeletal		N	N	N		N	N	N	N		
Superficial		1	1	11	1	"	1				
Others (Specify)		 -	_		· · · · · · · · · · · · · · · · · · ·	1		1			
N= new indication;	P= t	previ	ousl	cleare	d by FI	OA; E= ado	led under Ap	pendix E			
	•		•		•						
Other Indications or											
* Thyroid, Testicles						<u>. </u>					_
** B/M, B/PWD, C	FM((B)/P	WD	, CFM(B)/CFN	<i>I</i> (M)					
							WALLE OF ALCO	UPD DACE IS	(IEEDED)		
(P	LEAS	SE DO	NOT	WRITE B	ELOW TH	IS LINE-CON	TINUE ON ANOT evice Evaluation (HER PAGE IF I ODE)	ACCDED)		
				- onoution		,		•			

Prescription Use (Pe Ultras	r 21 sout	CFR nd D	. 801 evic	.109) ce Ind	ication	s Statem	ent Pag	e <u>5</u> of	<u>16</u> .		
510(k) Number (if k Device Name : <u>Diag</u>											
Fill out one											
Indications for use:	Dia	gnos	tie u	ltrasou	nd imag	ging or Dop	pler analysis	of the hum	an body as fo	llows:	
					Mod	de of Opera			10 11-1	Tissue	Other
Clinical Application	À	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Harmonic Imaging	(Specify)
Ophthalmic									ļ		
Fetal								<u> </u>			
Abdominal											
Intra-operative									Ì		
(Specify)										<u> </u>	
Intra-operative											
Neurological		1	ļ							ļ.,	
Pediatric										ļ	
Small Organ		1	1,,	N.T		N	N	N	N		1
(Specify) *		N	N	N		11	1		<u> </u>	<u> </u>	
Neonatal	\vdash	T									
Cephalic	1			ì						_	
Adult Cephalic		1									
Cardiac	T		T								
Transesophageal	 	1	T^{-}								
Transrectal	1	1-	1								
Transvaginal	\dagger	1	 								
Transurethral	+-	+-	 		1						
Intravascular	+	+-	1	—							
Peripheral Vascular	+	N	N	N		N	N	N	N		1
Laparoscopic		+*`	+								
Musculo-skeletal	+-	N	N	N		N	N	N	N	1	
Conventional		1	``	-	1 .						
Musculo-skeletal	+	N	N	N	1	N	N	N	N		
Superficial		^ `									
Others (Specify)		+									
N= new indication:	- P=	nrev	iousl	v clear	ed by F	DA: E= ad	ded under Ar	pendix E			
N- new mulcation	, 1 "	prov.	lousi	, cicar	ou o j = .	,	•	•			
Other Indications of	or M	odes:									_
* Thyroid, Testicle											
** B/M, B/PWD, 0	CFM	(B)/I	PWD	, CFM	(B)/CFI	M(M)					_
											_
	(PLEA	SE DO	TON	WRITE	BELOW TI	HIS LINE-CON	TINUE ON ANO	THER PAGE IF	NEEDED)		
				Concurre	nce of CD	RH, Office of D	Device Evaluation	(ODE)			

510(k) Number (11 k Device Name : <u>Dias</u>								<u> </u>			
Fill out one	forr	n for	each	ı ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	gnos	tic u	ltrasoui	nd imag	ing or Dop	pler analysis	of the hum	an body as fo	llows:	
					Mod	le of Opera	ıtion			T	Louis
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specif)
Ophthalmic										N	
Fetal		N	N	N	ļ	N	<u> </u>	N	N N	N N	
Abdominal		N	N	N		N	N	N	N	IN	+
Intra-operative (Specify)											ļ ·
Intra-operative Neurological											
Pediatric					<u> </u>	ļ <u> </u>		ļ			
Small Organ (Specify) *											-
Neonatal Cephalic											
Adult Cephalic										ļ	
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal					<u> </u>						
Transvaginal				I							
Transurethral											
Intravascular											+
Peripheral Vascular											-
Laparoscopic	\prod									 	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)								<u> </u>		<u> </u>	
N= new indication Other Indications (** B/M, B/PWD, (or M	odes:					ded under Ap	opendix E			
	(PLEA	SE DO	NOT	WRITE	BELOW TI	IS LINE-CON	TINUE ON ANO Device Evaluation	THER PAGE IF	NEEDED)		_

510(k) Number (if k Device Name : <u>Dia</u>	gnos	n):_ tic U	ltras	ound S	ystem S	DU-2200,	VA13R-050	<u>U</u>			
Fill out one	e for	n for	eacl	ı ultras	ound sy	stem or tra	nsducer.		-		
Indications for use:								of the hum	an body as fo	llows:	
					Mod	le of Opera	ation				T
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	L_	<u> </u>			 		 		N	 	+
Fetal		N	N	N.		N	N N	N	N		+
Abdominal		N	N	N		N	N	N	N		+
Intra-operative (Specify)											
Intra-operative			1			1					
Neurological						ļ					
Pediatric							_				┼──
Small Organ		Γ			1				1		1
(Specify) *		İ						ļ		-	
Neonatal					[
Cephalic	1		<u> </u>	<u></u>				 	<u> </u>		
Adult Cephalic											
Cardiac		N	N	N		N	N_	N_	N		
Transesophageal										 	
Transrectal										 	
Transvaginal											
Transurethral											
Intravascular			T							 	
Peripheral Vascular											
Laparoscopic							<u> </u>				
Musculo-skeletal	Ţ			Į							
Conventional					<u> </u>			 		 	+
Musculo-skeletal				1							
Superficial										1	
Others (Specify)				<u> </u>		<u> </u>		<u>ــــــــــــــــــــــــــــــــــــ</u>		1	
N= new indication Other Indications ** B/M, B/PWD,	or M	odes					ded under Ar	opendix E		144	
											
						WALLEY COL	TINUE ON ANO	THER PAGE IS	NEEDED)		

Ultra	sou	nd I)evi	ce Ind	ication	is Statem	ent Pag	e <u>8</u> of	<u>16</u> .		
510(k) Number (if k Device Name : <u>Diag</u>	now gnos	n) : _ tic U	ltras	ound S	ystem S	DU-2200,	VA20R-035	Ų			
Fill out one	for	n for	eac	h ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	gnos	tic u	ltrasou				of the huma	in body as fo	llows:	No.
					Mod	le of Opera	ation			T	1 61
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ											
(Specify) *		1		İ]					
Neonatal	-										1
Cephalic					'	1					
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal		1									
Transurethral											
Intravascular											
Peripheral Vascular											<u> </u>
Laparoscopic											
Musculo-skeletal											1
Conventional										ļ	<u> </u>
Musculo-skeletal					1				1		
Superficial										<u> </u>	
Others (Specify)	<u> </u>	<u> </u>	1						1		
N= new indication;	P= 1	orevi	ously	y cleare	d by FC	A; E= add	ed under App	pendix E			
Other Indications of	r Мо	des:				11.00					_
** B/M, B/PWD, C	FM(B)/P	WD	,CFM(I	3)/CFM	(M)					
-											_
											_
<u>(I</u>	PLEAS	SE DO					INUE ON ANOTI		EEDED)		_
				Concurren	OU OI CIN	an onle of De	D. ammon (C				

Prescription Use (P Ultra					lication	ıs Statem	ent Pag	ge <u>9</u> of	<u>16</u> .		
510(k) Number (if l Device Name : <u>Dia</u>				sound S	ystem S	DU-2200,	VA40R-035	U			
Fill out on	e for	m fo	r eac	h ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Die	onno	etic v	iltracou	nd imac	ring or Don	nler analysis	of the hum	an body as fo	llows.	
indications for use.	Dia	igno	suc i	masou.				or the num	an oody as ro	110 W 3.	
	T ,	T n	14	DIVD		de of Opera		l C-1	Combined	Tr:	T 04
Clinical	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude	Color Velocity	Combined (Specify)**	Tissue Harmonic	Other (Specify)
Application						- off)	Imaging	(-29))	Imaging	(54559))
							Doppler				
Ophthalmic	L										
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative							į				
(Specify)											
Intra-operative											
Neurological											
Pediatric											
Small Organ											
(Specify) *						······································					
Neonatal											
Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic									:		
Musculo-skeletal								 			
Conventional											
Musculo-skeletal											
Superficial											
Others (Specify)											
N= new indication;	P= p	revio	usly	cleared	by FD.	A; E= adde	d under App	endix E			
Other Indications	1.4.	1									
Other Indications or			I/D /	ODA (/D)	VCER#	M					
** B/M, B/PWD, CI	r M(t)/P\	wυ,(rim(B	//CFM(IVI)					
/D	LEASE	: DO N	IOT W	RITE REI	OW THIS	I INE CONTIN	IUE ON ANOTHI	ED DACE IE NIE	EDED)		٠.
(F.	-LAUI	, 101					ce Evaluation (OL		PDED)		
							• •				

Application Ophthalmic Fetal N N N N Abdominal N N N N Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)	on Power (Amplitude) Doppler N	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic
Ophthalmic Fetal N N N N N Abdominal N N N N N Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Cothers (Specify) N N N N N N N N N N N N N N N N N N N	N	N		Imaging
Fetal N N N N N N N N N N N N N N N N N N N		N		
Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)	N	14	N	N
(Specify) Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)		N	N	. N
Intra-operative Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Neurological Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Pediatric Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Small Organ (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)	· · · · ·			
(Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				ĺ
Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)		-		
Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)	****			
Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Peripheral Vascular Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				
Musculo-skeletal Conventional Musculo-skeletal Superficial Others (Specify)				ļ
Conventional Musculo-skeletal Superficial Others (Specify)		 		-
Musculo-skeletal Superficial Others (Specify)				
Others (Specify)	•			· · · · · · · · · · · · · · · · · · ·
Maria di di di Dani di Dani di Dani di di				
N= new indication; P= previously cleared by FDA; E= added to	under Ap	pendix E		7i
Other Indications on Made				
Other Indications or Modes: ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)				
Bim, Bit wb, Crim(B)/Fwb,Crim(B)/Crim(M)				
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE	E ON ANOT	HER PAGE IF NE	EEDED)	***
Concurrence of CDRH, Office of Device I				
/				
Prescription Use				
1 escription cos				

Device Name: <u>Dia</u> Fill out on								<u>5WU</u>			
Indications for use:								of the hum	nan body as fo	llows:	
					Мо	de of Oper	ation				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify) Intra-operative											
Neurological		<u> </u>				ļ					
Pediatric		ļ			ļ					ļ	
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic					T						_
Cardiac					T						
Transesophageal						<u> </u>				ļ	
Transrectal			l								
Transvaginal										<u> </u>	
Transurethral											
Intravascular	T									ļ	
Peripheral Vascular			Π.							ļ	
Laparoscopic											1
Musculo-skeletal											1
Conventional		<u> </u>	<u>L</u> .		1			1			
Musculo-skeletal Superficial											
Others (Specify)	—	1									
N= new indication	P= 1	orevi	ously	cleare	d by FI	A; E= ado	led under Ap	pendix E			
Other Indications				<u></u>							-
** B/M, B/PWD, 0	CFM	(B)/P	WD	,CFM(I	3)/CFM	(M)				······	-
											-

Prescription Use (Pe Ultras	er 21 oun	d D	evic	e Indi	cations	s Stateme	ent Page	<u>12</u> o	f <u>16</u> .		
510(k) Number (if k Device Name : <u>Dia</u>	now gnos	n) : _ tic U	ltras	ound S	ystem S	 DU-2200,	VA57R-037:	5HU			•
Fill out one											
Indications for use:	Dia	ignos	stic u	ltrasou				of the hum	an body as fo	llows:	
						le of Opera		T- 1	Combined	Tissue	Other
Clinical	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude	Color Velocity	(Specify)**	Harmonic	(Specify)
Application						Боррис) Doppler	Imaging		Imaging	
Ophthalmic	_			<u> </u>			1-11-				
Fetal		N	N	N	 	N	N	N	N	N	
Abdominal	-	N	N	N		N	N	N	N	N	
Intra-operative	 	<u> </u>	<u> </u>		1						
(Specify)											
Intra-operative		1									
Neurological]						
Pediatric										<u> </u>	
Small Organ								1			1
(Specify) *				<u> </u>	<u></u>			<u> </u>			
Neonatal				1	1						
Cephalic								ļ		 	
Adult Cephalic			_				.			 	
Cardiac		<u> </u>			ļ	ļ			 		
Transesophageal											
Transrectal		<u> </u>	<u> </u>	<u> </u>	<u> </u>			<u> </u>		ļ	
Transvaginal			<u> </u>	<u> </u>		ļ					
Transurethral			<u> </u>					ļ			
Intravascular			1_			ļ					
Peripheral Vascular		1_	<u> </u>								-
Laparoscopic		\perp		<u> </u>		<u> </u>			- 		
Musculo-skeletal		1	1						ł		
Conventional		-	_	 	 					 	
Musculo-skeletal				1							
Superficial		-	╀	ļ		 		-		 	
Others (Specify)	<u> </u>			ــــــــــــــــــــــــــــــــــــــ	<u> </u>	<u> </u>	1 1 1 4	l I		<u> </u>	
N= new indication Other Indications				y cleare	ed by Fl	JA; E= ado	ied under Ap	pendix E			<u> </u>
** B/M, B/PWD, G	FM	(B)/I	PWT	.CFM(B)/CFM	1(M)			, , , , , , , , , , , , , , , , , , , ,		_
D/M, D/I WD,	JA 171	<u> </u>	. ,,	,	- <i>j.</i>	<u> </u>					
	(PLEA	SE DO) NOT	WRITE B	ELOW TH	IS LINE-CON	TINUE ON ANOT	HER PAGE IF	NEEDED)		
				Concurre	nce of CD	RH, Office of D	evice Evaluation (UDE)			

510(k) Number (if Device Name : <u>Di</u>	knov agno:	vn): stic U	Jltras	ound S	ystem S	DU-2200,	\$017-035U				
Fill out on	e for	m fo	r eac	h ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Di	agno	stic u	ıltrasou	nd imag	ging or Do	opler analysis	of the hum	an body as fo	ollows:	
					Мос	le of Opera	ation		-		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		ļ					1				
Abdominal				N		N	N			N	
Intra-operative (Specify) Intra-operative											
Neurological											
Pediatric											1
Small Organ	Ī										
(Specify) *											
Neonatal											
Cephalic	ļ										
Adult Cephalic									<u> </u>		ļ
Cardiac	<u> </u>	N	N	N	N	N	N	N	N	N	
Transesophageal	<u> </u>						ļ				
Transrectal	├						ļ		ļ		<u> </u>
Transvaginal	ļ								ļ		<u> </u>
Transurethral	ļ						ļ				ļ
Intravascular	<u> </u>										
Peripheral Vascular											
Laparoscopic	 		 								
Musculo-skeletal] .
Conventional									1		
Musculo-skeletal											1
Superficial Others (Specific)									-		
Others (Specify)	<u> </u>		ليل				<u> </u>		1		<u> </u>
N= new indication;	P= p	revio	ously	cleared	by FD	A; E= adde	ed under App	endix E			
Od	. 3.7.	1									
Other Indications or			100	TEL CO	MILITA	CIENTAL DIVI	ENGO DO	UD CENT	S) (OIII)	 	
** B/M, B/PWD, C	rM(3)/P\	wD,(rm(R	yrwD,	CFM(R)/C	.гм(м),в/С	wD,CFM(E	s)/CWD		
/D	LEAS	2 DO N	IOT W	RITERE	OW THIS	I INE-CONTI	NUE ON ANOTH	ED DAGE IE NE	EDED		
(P	~	2001					ice Evaluation (OI		LUEU)		

Prescription Use (Per 21 CFR 801.109) Ultrasound Device Indications Statement Page 14 of 16.											
510(k) Number (if known):											
Fill out one form for each ultrasound system or transducer.											
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:											
Mode of Operation											
Clinical Application	A	В	M	PWD	CWD	Color	Power	Color	Combined	Tissue	Other
						Doppler	(Amplitude	Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
		-					Doppler	imaging		Imaging	
Ophthalmic											
Fetal											
Abdominal		 		N		N	N				
Intra-operative											
(Specify)											
Intra-operative											
Neurological											
Pediatric		N	N	N	N	N	N	N	N		
Small Organ					1					į	
(Specify) *						ļ					
Neonatal					ł						
Cephalic				ļ	_						
Adult Cephalic					ļ.,	ļ	ļ <u>.</u>	N.T.			
Cardiac		N	N	N	N	N	N	N	N	<u> </u>	
Transesophageal			ļ	ļ	<u> </u>						<u> </u>
Transrectal					ļ		- 				
Transvaginal		_		<u> </u>	ļ		 				
Transurethral	<u> </u>			ļ	╂	ļ	 		+	 	
Intravascular Peripheral Vascular				ļ	-				-		
Laparoscopic		 	_		 	-	 	 	+		
Musculo-skeletal			 -	-	1	<u> </u>					
Conventional										}	
Musculo-skeletal	ļ		-		 	 				1	
Superficial				,	ľ						
Others (Specify)					i						
N= new indication;	P= p	revi	ously	cleare	d by FD	A; E= add	ed under App	endix E			·
Other Indications or											_
** B/M, B/PWD, C	FM(B)/P	WD,	CFM(E	3)/PWD	,CFM(B)/	CFM(M),B/C	WD,CFM(B)/CWD		_
											-
· · · · · · · · · · · · · · · · · · ·	E E 4 0	EDO	NOT "	VDITE ST	I OW TIP	CLINE CONT	INITIE ON ANOTE	JED DACE IE N	EEDED)		-
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)										-	

Prescription Use (Po Ultras	er 21 soun	CFF nd D	R 80: evid	1.109) ce Ind i	cation	s Stateme	ent Page	e <u>15</u> o	f <u>16</u> .		
510(k) Number (if known): Device Name: Diagnostic Ultrasound System SDU-2200, TV11R-055U											
Fill out on	e for	m fo	r eac	h ultras	ound sy	stem or tra	ınsducer.				
Indications for use:	Dia	agnos	stic u	ıltrasou	nd imag	ging or Dop	opler analysis	of the hum	an body as fo	llows:	
					Mo	de of Opera	ation				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic							<u> </u>	<u> </u>			
Fetal		N	N	N	ļ	N	N	N_	N		
Abdominal		<u> </u>			ļ			 			ļ
Intra-operative (Specify)											
Intra-operative						}					
Neurological	<u> </u>	ļ	<u> </u>		<u> </u>	<u> </u>	ļ			<u> </u>	
Pediatric	<u> </u>	 —	<u> </u>		<u> </u>	ļ	 				4
Small Organ (Specify) *											
Neonatal					1.				İ		
Cephalic		<u> </u>	ļ		 	 			 		
Adult Cephalic	<u> </u>					<u> </u>		ļ			
Cardiac	ļ	1	<u> </u>	ļ	ļ						<u> </u>
Transesophageal	 	1	<u> </u>		ļ	ļ.,,		37			
Transrectal	Ь	N	N	N	ļ	N	N N	N N	N		<u> </u>
Transvaginal	<u> </u>	N	N	N		N	N	N	N		
Transurethral	ļ	<u> </u>	₩	ļ	4	ļ				ļ	
Intravascular		ļ	├ ─	ļ				 			
Peripheral Vascular	_	 	ļ	ļ	ļ	<u> </u>	- 	 	-		
Laparoscopic	 	ļ	 	 	 			ļ	ļ	ļ	
Musculo-skeletal		1		İ					1		
Conventional	-	┼	 	<u> </u>	<u> </u>	ļ		 			
Musculo-skeletal											
Superficial	+	 	-		 	 					<u> </u>
Others (Specify)	<u></u>	┸	! 		11 . EE	M. F 11	ladam Am	andir E		1	
N= new indication;	P= 1	previ	ousiy	cleare	a by FL	A; E= add	ied under App	pendix is			
Other Indications o	- NA 0	dog.									
** B/M, B/PWD, C			WD	CEMO	3)/CEM	(M)					-
D/IVI, D/F WD, C	T. 1AT	<i>۲ از</i> دن	WD,	,C1 1V1(1	<i>5 ji</i> C1 1V1	(171)					_
											_
(PLEAS	SE DO					INUE ON ANOTI		IEEDED)		-
				Concurren	ce of CDR	H, Office of De	evice Evaluation (C	DDE)			
		,									

Prescription Use (Per 21 CFR 801.109) Ultrasound Device Indications Statement Page 16 of 16.											
510(k) Number (if known):											
Fill out one form for each ultrasound system or transducer.											
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:											
Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic		_									
Fetal											
Abdominal								•			
Intra-operative (Specify)											
Intra-operative					<u> </u>						
Neurological			l								
Pediatric								<u> </u>			
Small Organ					İ						
(Specify) *					<u> </u>				<u> </u>		<u> </u>
Neonatal	1										
Cephalic			<u> </u>			<u> </u>			 		
Adult Cephalic			ļ			ļ		ļ	<u> </u>		
Cardiac	ļ				<u> </u>			ļ	- 		ļ
Transesophageal	ļ	_	ļ					NT.			
Transrectal	 	N	N	N		N	N	N	N		
Transvaginal		<u> </u>	<u> </u>			ļ	 		 		
Transurethral	<u> </u>	!	<u> </u>								ļ
Intravascular		<u> </u>	ļ								ļ
Peripheral Vascular	ļ					-					ļ
Laparoscopic	ļ	<u> </u>	ļ				 	 			
Musculo-skeletal					l						
Conventional		├	<u> </u>		 		 				
Musculo-skeletal			1		1						
Superficial Others (Specify)	├	_	├				<u> </u>	 	 		
Others (Specify) N= new indication;	D			Lalaara	l by PD	A · E - add	ad under Ans	andiv F	1	<u> </u>	1
			ousiy	cieare	i oy FD	A, E- a00	eu under App	Jenuix E			
Other Indications of			1115	OF C	NOTE:	0.0					-
** B/M, B/PWD, C	rM(B)/P	wD,	CFM(E)/CFM	(M)					-
											-
	LEAS	E DO	NOT V	VRITE BE	LOW TH	S LINE-CONT	INUE ON ANOTH	IER PAGE IF N	EEDED)		-
Concurrence of CDRH, Office of Device Evaluation (ODE)									-		